

## REMARKS

### I. Status of the Claims

Claims 39 and 44-47 are now pending in the application. Claims 1-38 and 40-43 were previously canceled.

### II. Reconsideration after Final Rejection

Applicants respectfully request the Examiner's reconsideration of the final rejections of the pending claims in view of the cited art, as discussed herein. Reconsideration after final rejection is proper because the arguments place the claims in allowable condition and do not require further search or examination.

### III. Rejection Under 35 U.S.C. § 103

Claims 39 and 44-47 stand rejected under 35 U.S.C. § 103(a) over WO 00/44375 to Harper ("Harper") in view of U.S. Patent No. 6,335,361 to Hamilton ("Hamilton").

Applicants respectfully request the Examiner's reconsideration of the final rejections based on the patentable distinctions of the claimed methods over the prior art, as discussed herein. Applicants respectfully submit that a *prima facie* case of obviousness has not been established for the rejected claims.

Under §103, (i) the scope and content of the prior art are to be determined; (ii) differences between the prior art and the claims at issue are to be ascertained; and (iii) the level of ordinary skill in the pertinent art resolved. *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1 (1966). "Against this background the obviousness or nonobviousness of the subject matter is determined." *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1729-30 (2007).

*There is no reason for the skilled artisan to combine the references as suggested in the Office Action.*

None of the prior art references nor their combination describes or suggests to a skilled artisan the claimed method of inhibiting the loss of learning ability or increasing the learning ability of an aged companion pet in need of such treatment. The Harper reference describes reducing or treating "oxidative stress" in a dog or cat by

administering vitamin E, vitamin C, taurine, carotenoid, lycopene, lutein, and/or other components, such as trace minerals, selenium, copper, zinc, and manganese. Harper enumerates various oxidative stress related disorders, including aging and neurodegenerative diseases, among others. See P. 13, lines 8-24. Harper lacks any description of administering a diet of vitamin E, vitamin C, which further includes at least one of  $\alpha$ -lipoid acid, L-carnitine, and mixtures thereof. Second, Harper lacks any suggestion of treating an aged animal to inhibit loss of learning ability or to increase learning ability to an aged companion pet needing such a treatment.

The Hamilton reference does not account for the deficiencies of the Harper reference. Hamilton provides an invention “related to the prevention and amelioration of memory deficits related to aging and other causes.” Col. 1, lines 12-16. Hamilton further provides for administering carnitine, lipoic acid, and optionally coenzyme Q10 and/or creatine to “discourage age-related memory loss and provide improved memory in older individuals and others with unhealthy mitochondria.” Col. 7, lines 13-17.

But the teachings of the Hamilton reference repeatedly pertain to addressing memory impairment in humans. Hamilton discusses the complexity and variability of different methods available for characterizing memory losses in humans, outlining the distinction between benign memory loss and degenerative dementia and the underlying mechanisms for such cognitive disorders, among others. See *e.g.*, Col. 1, line 17-Col. 4, line 19. Hamilton mentions learning as part of a comprehensive diagnostic criteria test (the International Psychogeriatric Association’s/World Health Organization’s aging-associated cognitive decline (AACD)) stated to be more comprehensive than the National Institute of Mental Health’s age-associated memory impairment (AAMI) test, because it tests cognitive domains of memory and learning, attention and concentration, thinking, language and visuospatial functioning. Col. 2, lines 27-64; See also, EXAMPLE - Environmental Toxin Exposure, Col. 12, line 54. Hamilton does not suggest diets for companion animals nor enhancement of learning using such diets.

The differences between the prior art and the claimed invention support the patentability of the claimed invention. Importantly, nothing in the cited references provides any directive to one of skill in the art to select certain compounds (from Harper) used to reduce oxidative stress in pets and combine them with certain compounds (from Hamilton) used to treat memory related disorders in humans. Nor is there any suggestion that any such combinations would be capable of inhibiting loss of learning ability or increasing learning ability of an aged companion pet in need thereof as in the current claims.

Conclusory statements do not support a prima facie case.

The Federal Circuit has recently stated, “while the KSR Court rejected a rigid application of the teaching, suggestion, or motivation (“TSM”) test in an obviousness inquiry, the court acknowledged the importance of identifying ‘a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does’ in an obviousness determination.” *Takeda Chem. Ind. V. Alphapharm Pty, Ltd.*, 492 F.3d 1350, 1356-57 (Fed. Cir. 2007); citing *KSR*, 127 S. Ct. at 1731.

As such, an obviousness rejection cannot state merely state conclusory allegations of obviousness without providing a sound basis for how and importantly why the prior art met the claim limitations. See *KSR*, 127 S. Ct. at 1741 (“[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.”).

As discussed above, the cited references do not provide any apparent rationale to support the concept that reducing oxidative stress and/or reducing memory loss would improve learning or diminish loss of learning in aged animal. While the “Examiner does not agree that the actual physiological and biochemical processes involved with learning and memory is different,” the Examiner’s opinion (which notably is not taken as official notice) is merely a conclusory statement that Applicants respectfully submit cannot adequately support an obviousness rejection. It still remains that the requisite

link between memory and learning is absent in the general knowledge in the prior art upon which the final rejection relies. See Non-Final Office Action, Page 7, lines1-9.

Learning and memory are recognized in the art as separate concepts.

Glossing over the distinction and different physiological and biochemical mechanisms by which learning and memory occur inappropriately neglects the complexity and unpredictability of these arts, as understood and appreciated by those of skill in the art. Notably, in Example 1 of Applicants' specification, beagle dogs were equally matched with respect to initial learning and memory capabilities. Thus, the dogs were equally matched on the basis of cognition prior to diet intervention and testing based on problem-solving tasks for landmark discrimination learning tasks. The dogs receiving the test diet were the only ones who demonstrated highly significant differences in landmark discrimination tasks and had fewer errors. Thus, learning in these animals was assessed and determined to be independent of memory level.

Here the issue is whether it have been obvious to one of skill in the art, familiar with the distinctions between mental function in humans and companion animals and further aware of the complexities and differences in learning and memory, to arrive at the claimed method by combining the prior art's teachings. In other words, would one of skill in the art have had an apparent reason to select compounds from each respective disclosure to arrive at the claimed methods of inhibiting loss of learning or increasing learning ability? Applicants respectfully submit that the prior art does not suggest the claimed methods, especially when the entirety of the teachings of the Hamilton reference is considered, which highlights the complexities in characterizing memory-loss alone and would discourage a skilled artisan to believe such teachings should be extended into an entirely distinct area of cognitive functioning, namely, learning. Moreover, the gap remains between the claimed methods of improving learning and/or diminishing loss of learning in an aged companion animal and the prior art's teachings related to general oxidative stress and ageing related memory loss under the complex penumbra of improving cognitive function.

The Examiner goes on to note that Hamilton discusses cognition and cites Stedman's Medical Dictionary defining "cognition" as a generic term embracing the mental activities associated with thinking, learning, and memory. Applicants do not disagree that cognition broadly encompasses learning and memory. However, learning and memory are distinct species of cognition; moreover each is defined and categorized as a different discipline to those of skill in the art. For example, learning can be defined as "a relatively long-lasting adaptive behavioral change occurring as a result of experience" as where memory can be defined as "that mental faculty by which sensations, impressions, and ideas are recalled." See App. A: Dorland's Medical Dictionary Online definitions of learning and memory. These distinct aspects of cognition do not share identity with one another.

The Examiner's reliance on the prior art's recitation of the genus of "cognition" does not provide the necessary teaching or suggestion to arrive at a sub-species of "learning." Reconsideration is requested in light of the following discussion.

*Species claims are not per se unpatentable over a disclosed genus.*

A claim directed to a specific species can be patentable over the cited art describing a broad genus. See e.g., *Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1262 (Fed. Cir. 1989). In *Perricone v. Medicis Pharmaceutical Corp*, 432 F.3d 1368 (Fed. Cir. 2005), the Federal Circuit considered whether claims directed to a method of treating sunburned skin were rendered invalid under inherent anticipation over a prior art reference applying a topical skin composition having the same skin benefit compound. The Federal Circuit held that certain claims (directed to a narrow method for treating a skin sunburn comprising topically applying to the skin sunburn a fatty acid ester of ascorbic acid) were patentable over the prior art. However, other broader claim directed to methods of treating skin disorders or skin damage were invalid. The Court stated that a method of treating a sunburn (a narrow species of the genus of skin disorders or skin damage) is patentable over a reference that applies the same composition to skin, however, does not disclose applying the lotion to skin

sunburn. See e.g., *Perricone*, 432 F.3d at 1374, 1377-80. The Federal Circuit held that “there is an important distinction between topical application to skin for the purpose of avoiding sunburn, and the much narrower topical application to skin sunburn. The [prior art] is silent about any sunburn prevention or treatment benefits, not to mention the mechanisms underlying such uses. If [the prior art] did teach sunburn prevention, as well as the mechanism behind that prevention, those teachings might suggest that Dr. Perricone’s sunburn treatment claims would have been obvious.” *Perricone*, 432 F.3d at 1379. Since the prior art failed to describe narrowly claimed methods of applying the composition to treat sunburn, the particular claims directed to those methods were patentable.

In contrast, the present rejection is even more removed from the prior art than in *Perricone*, because it is not an anticipation rejection (where the same composition is administered to a companion animal), but instead relies on the obviousness of a selective combination of certain compounds from the prior art that are necessary to arrive at the claimed methods. The claimed methods are patentable over the cited prior art for similar reasons that the methods of treating sunburns were held patentable in *Perricone*. The combination of the prior art generally pertains to reducing oxidative stress and cognitive disorders. However, the present invention claims methods of inhibiting loss of or increasing learning ability, which are a particular sub-species of cognitive function. The prior art fails to describe anything related to improving learning or diminishing learning loss in an aged animal and further entirely fails to suggest any link between the oxidative stress/memory loss and learning.

In other words, nothing in the knowledge of the prior art would suggest to one of skill in the art an apparent reason to select certain prior art compounds to arrive at the claimed invention, nor would the prior art support any reasonable expectation of success. Thus, since the claimed methods are directed to a specific method of treating an animal having a learning loss or requiring improved learning, which was neither recognized nor suggested by the prior art, Applicants respectfully submit that these claims are patentable. The prior art is silent with regard to the requisite link between

general oxidative stress, memory loss, or the genus of cognition with inhibited learning loss or improved learning. Absent some teaching or knowledge in the prior art, neither the Examiner's unsupported conclusory statements of the relationship between learning and memory, nor impermissible hindsight reconstruction, can properly support a *prima facie* case of obviousness. As such, withdrawal of the final rejection and allowance of Claims 39 and 44-47 are respectfully requested.

### **CONCLUSION**

For the reasons discussed above Applicants believe that claims 39 and 44-47 are in an allowable condition and that consideration after final is proper. Applicants respectfully request an early notice of allowance, or in the alternative an Advisory Action stating whether the arguments can be considered at this time.

Respectfully submitted,

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